Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 206111
Company: BOEHRINGER INGELHEIM

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=206111)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s042,208658s028lbl.pdf#page=44)

Products on NDA 206111

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	5MG;500MG	TABLET;ORAL	Prescription	AB	Yes	No
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	5MG;1GM	TABLET;ORAL	Prescription	AB	Yes	No
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	12.5MG;500MG	TABLET;ORAL	Prescription	AB	Yes	No
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	12.5MG;1GM	TABLET;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 206111

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
08/26/2015	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206111lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/206111Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206111Orig1s000TOC.cfm)	

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/30/2023	SUPPL-42	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s042,208658s028lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/206073Orig1s036; 206111Orig1s042; 208658Orig1s028; 212614Orig1s020ltr.pdf)	
06/20/2023	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s038s039,208658s025s026lbl.pdf)	
06/20/2023	SUPPL-38	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s038s039,208658s025s026lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/206111Orig1s038,s039;208658Orig1s025,s026ltr.pdf)	
02/06/2023	SUPPL-33	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s033lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/206111Orig1s033,208658Orig1s021ltr.pdf)	
10/13/2022	SUPPL-36	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206111s036lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/204629Orig1s039,206073Orig1s033,206111Orig1s036,208658Orig1s023ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/21/2022	SUPPL-31	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206111s031lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/204629Orig1s034;206073Orig1s031;206111Orig1s031;208658Orig1s017ltr.pdf)**	
06/11/2021	SUPPL-26	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206111s025s026lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204629Orig1s028, s029; 206073Orig1s027, s030; 206111Orig1s025, s026; 208658Orig1s013, s015; 212614Orig1s008, s010ltr.pdf)**	
06/11/2021	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206111s025s026lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204629Orig1s028, 206073Orig1s027, 206111Orig1s025, 208658Orig1s013, 212614Orig1s008ltr.pdf)**	
01/24/2020	SUPPL-22	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206111s022lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/204629Orig1s023,206073Orig1s023,206111Orig1s022,208658Orig1s009ltr.pdf)**	
10/26/2018	SUPPL-18	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/206111s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/204629Orig1s018,206073Orig1s019,206111Orig1s018,208658Orig1s006ltr.pdf)**	
12/13/2017	SUPPL-15	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/206111s015lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/206111Orig1s015,208658Orig1s004ltr.pdf)**	
12/23/2016	SUPPL-4	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s004lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/206111Orig1s004ltr.pdf)**	
07/08/2016	SUPPL-9	Labeling-Package Insert, Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/206111Orig1s001,s006,s009ltr.pdf)**	
07/08/2016	SUPPL-6	Labeling-Package Insert, Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/206111Orig1s001,s006,s009ltr.pdf)**	
07/08/2016	SUPPL-1	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/206111Orig1s001,s006,s009ltr.pdf)**	
05/06/2016	SUPPL-8	Manufacturing (CMC)		Label is not available on this site.
12/04/2015	SUPPL-2	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206111s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/206111Orig1s002ltr.pdf)**	

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Labels for NDA 206111

Therapeutic Equivalents for NDA 206111

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 206111
Company: BOEHRINGER INGELHEIM

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=206111)

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Products on NDA 206111

Approval Date(s) and History, Letters, Labels, Reviews for NDA 206111

Labels for NDA 206111

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/30/2023	SUPPL-42	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s042,208658s028lbl.pdf)**	
06/20/2023	SUPPL-39	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s038s039,208658s025s026lbl.pdf)**	
06/20/2023	SUPPL-38	Efficacy-New Patient Population	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s038s039,208658s025s026lbl.pdf)**	
02/06/2023	SUPPL-33	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206111s033lbl.pdf)**	
10/13/2022	SUPPL-36	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206111s036lbl.pdf)**	
03/21/2022	SUPPL-31	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206111s031lbl.pdf)**	
06/11/2021	SUPPL-26	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206111s025s026lbl.pdf)**	
06/11/2021	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206111s025s026lbl.pdf)**	
01/24/2020	SUPPL-22	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206111s022lbl.pdf)**	
01/24/2020	SUPPL-22	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206111s022lbl.pdf)**	
10/26/2018	SUPPL-18	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/206111s018lbl.pdf)**	
10/26/2018	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/206111s018lbl.pdf)**	
12/13/2017	SUPPL-15	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/206111s015lbl.pdf)**	
12/23/2016	SUPPL-4	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s004lbl.pdf)**	
07/08/2016	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)**	
07/08/2016	SUPPL-9	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)**	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/08/2016	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)**	
07/08/2016	SUPPL-6	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)**	
07/08/2016	SUPPL-1	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206111s009lbl.pdf)**	
12/04/2015	SUPPL-2	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206111s002lbl.pdf)**	
08/26/2015	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206111lbl.pdf)**	

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Therapeutic Equivalents for NDA 206111

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Products on NDA 206111

Approval Date(s) and History, Letters, Labels, Reviews for NDA 206111

Labels for NDA 206111

Therapeutic Equivalents for NDA 206111

SYNJARDY

TABLET;ORAL; 5MG;500MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	5MG;500MG	TABLET;ORAL	Prescription	Yes	AB	206111	BOEHRINGER INGELHEIM

Showing 1 to 1 of 1 entries

TABLET;ORAL; 5MG;1GM
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	5MG;1GM	TABLET;ORAL	Prescription	Yes	AB	206111	BOEHRINGER INGELHEIM

Showing 1 to 1 of 1 entries

TABLET;ORAL; 12.5MG;500MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	12.5MG;500MG	TABLET;ORAL	Prescription	Yes	AB	206111	BOEHRINGER INGELHEIM

Showing 1 to 1 of 1 entries

TABLET;ORAL; 12.5MG;1GM
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
SYNJARDY	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE	12.5MG;1GM	TABLET;ORAL	Prescription	Yes	AB	206111	BOEHRINGER INGELHEIM

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